

bit, hammerhead, pin driver, and saw blade.

(b) *Classification*. Class I.

[55 FR 48440, Nov. 20, 1990]

§ 878.4830 Absorbable surgical gut suture.

(a) *Identification*. An absorbable surgical gut suture, both plain and chromic, is an absorbable, sterile, flexible thread prepared from either the serosal connective tissue layer of beef (bovine) or the submucosal fibrous tissue of sheep (ovine) intestine, and is intended for use in soft tissue approximation.

(b) *Classification*. Class II.

[54 FR 50738, Dec. 11, 1989]

§ 878.4930 Suture retention device.

(a) *Identification*. A suture retention device is a device, such as a retention bridge, a surgical button, or a suture bolster, intended to aid wound healing by distributing suture tension over a larger area in the patient.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[53 FR 23872, June 24, 1988, as amended at 59 FR 63010, Dec. 7, 1994]

§ 878.4950 Manual operating table and accessories and manual operating chair and accessories.

(a) *Identification*. A manual operating table and accessories and a manual operating chair and accessories are non-powered devices, usually with movable components, intended to be used to support a patient during diagnostic examinations or surgical procedures.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[53 FR 23872, June 24, 1988, as amended at 54 FR 13828, Apr. 5, 1989; 59 FR 63010, Dec. 7, 1994]

§ 878.4960 Operating tables and accessories and operating chairs and accessories.

(a) *Identification*. Operating tables and accessories and operating chairs and accessories are AC-powered or air-powered devices, usually with movable components, intended for use during di-

agnostic examinations or surgical procedures to support and position a patient.

(b) *Classification*. Class I.

[55 FR 48440, Nov. 20, 1990]

§ 878.5000 Nonabsorbable poly(ethylene terephthalate) surgical suture.

(a) *Identification*. Nonabsorbable poly(ethylene terephthalate) surgical suture is a multifilament, nonabsorbable, sterile, flexible thread prepared from fibers of high molecular weight, long-chain, linear polyesters having recurrent aromatic rings as an integral component and is indicated for use in soft tissue approximation. The poly(ethylene terephthalate) surgical suture meets U.S.P. requirements as described in the U.S.P. Monograph for Nonabsorbable Surgical Sutures; it may be provided uncoated or coated; and it may be undyed or dyed with an appropriate FDA listed color additive. Also, the suture may be provided with or without a standard needle attached.

(b) *Classification*. Class II.

[56 FR 24685, May 31, 1991]

§ 878.5010 Nonabsorbable polypropylene surgical suture.

(a) *Identification*. Nonabsorbable polypropylene surgical suture is a monofilament, nonabsorbable, sterile, flexible thread prepared from long-chain polyolefin polymer known as polypropylene and is indicated for use in soft tissue approximation. The polypropylene surgical suture meets United States Pharmacopeia (U.S.P.) requirements as described in the U.S.P. Monograph for Nonabsorbable Surgical Sutures; it may be undyed or dyed with an FDA approved color additive; and the suture may be provided with or without a standard needle attached.

(b) *Classification*. Class II.

[56 FR 24685, May 31, 1991]

§ 878.5020 Nonabsorbable polyamide surgical suture.

(a) *Identification*. Nonabsorbable polyamide surgical suture is a nonabsorbable, sterile, flexible thread prepared from long-chain aliphatic polymers Nylon 6 and Nylon 6,6 and is indicated for use in soft tissue approximation.